Submitter : **Dr. Douglas Quarles** **Date: 11/06/2006**

Organization : **Augusta Urology Surgery Center, LLC**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1506-P2-1009-Attach-1.DOC

#1009

November 01, 2006

Leslie V. Norwalk, Esq., Acting Administrator
Centers for Medicare & Medicaid Services
Dept. of Health and Human Services
Attention: CMS-1506-P
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, Southwest
Washington, District of Columbia 20201

Dear Administrator Norwalk:

I am currently a member of a seven-physician urology practice in Augusta, Georgia. We have a freestanding ambulatory surgery center as well as three clinic offices in the surrounding area. We serve patients covered by private health insurance as well as an ever-growing Medicare/Medicaid and indigent population in our clinics as well as our surgery center. I am writing because there is current legislation pending that will drastically reduce Medicare ASC payments.

Augusta Urology Surgicenter is a high quality, cost effective alternative to the hospital. We play an important role in holding down the costs of medical care in the Augusta area. Therefore, I was disturbed to learn that Congress is considering proposals to cut our Medicare payments. Urology is expected to be the third hardest hit specialty in reductions to ASC Medicare payments. Mostly, this is due to the large reduction in the payment of the second most frequently performed Medicare ASC urologic procedure, prostate biopsy (CPT 55700). Payments for this procedure will be reduced by 39% in 2007 and even further in 2008.

I understand elected officials want to limit our facility fees to the hospital outpatient department rate (HOPD). While on paper a few of our rates appear to be higher than the hospital rate, this is very misleading. Our facility fee has to cover all the costs of our surgery, including radiology services. The hospital gets to bill separately for each of these as well as many other services. They also get to pass through the costs of new technology, but we cannot. By any standard, the hospital almost always gets paid much more for this and other procedures performed in this setting (outpatient).

As the actual impact of these reductions will vary among the different specialties, ultimately the financial viability of these enterprises will be negatively impacted. Instead of accomplishing the goal of more competition within the healthcare arena this will result in still fewer choices for Medicare recipients. This reimbursement philosophy greatly discourages the efficiency and excellence exhibited by a majority of surgery centers and does nothing to realistically reduce costs.

The proposal to reimburse surgery centers somewhere between 60-65% of hospital outpatient department rates is simply not adequate. Surgery centers must pay competitive wages to nurses and

other staff the same as hospitals. The increase in the cost for liability insurance coupled with the difficulty of obtaining coverage in some states has had a huge financial impact on surgery centers just as hospitals have experienced. Rent, taxes and operating supplies probably consume more of most surgery centers budgets than those of hospitals. Most surgery centers have 20-25 employees and are small businesses. They don't have the political clout and resources of large hospital organizations. If this were not so, this entire discussion and proposal would never had occurred.

Aligning the payment systems for ASCs with those of the hospital outpatient departments will improve the transparency of cost. In addition, improving the quality of the data generated by ASCs and hospital outpatient departments could only be positive for Medicare beneficiaries. We believe that the benefits to the taxpayer AND the Medicare consumer will be maximized by aligning the payment policies to the greatest extent permitted under the law.

In closing, we also believe the ASC list reform proposed by CMS is simply too limited. CMS should expand the list of procedures to mirror that of the HOPDs. ASCs are state licensed and Medicare approved facilities. Additionally a substantial number of ASCs are accredited by AAAHC and other respected accrediting bodies just as hospital outpatient departments. To allow HOPDs to perform any outpatient procedure but then restrict many of the same procedures from being performed in an ASC frankly makes no sense. The same physicians performing these procedures in the hospital outpatient suites are also owners and practitioners in ASCs. There is no deterioration in their surgical skills between facilities that we are aware. CMS should exclude only those procedures that are on the inpatient list.

Since ASCs must compete for labor, pay substantial sums for liability insurance and taxes, maintain all of the regulations mandated by CMS in addition to providing a safe, efficient and highly professional environment for Medicare patients, it is only equitable that CMS consider ASCs as equal partners in the medical services delivery system and not substandard enterprises.

Respectfully,

J. Douglas Quarles, Jr., M.D.
Augusta Urology Associates Surgicenter, LLC
Augusta, Georgia 30901

CMS-1506-P2-1010

Submitter : | **Date:** 11/06/2006

Organization : Cytyc Corporation

Category : Device Industry

Issue Areas/Comments

GENERAL

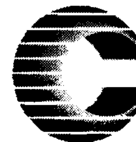
GENERAL

please see attachment

CMS-1506-P2-1010-Attach-1.DOC

#1010

C Y T Y C



November 6, 2006 **_Via Electronic Submission_**

Leslie Norwalk, Esq.
Acting Administrator, Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attn: CMS-1506-P
Mail Stop: C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: CMS-1506-P2 – Medicare Program; Ambulatory Surgical Center Payment System and CY 2008 Payment Rates

Dear Ms. Norwalk:

Cytyc welcomes the opportunity to comment on the Centers for Medicare & Medicaid Services' ('CMS') Medicare Program Ambulatory Surgical Center Payment System and CY 2008 Payment Rates published in the Federal Register (Vol. 71, No.163) on August 23, 2006. In particular, we wish to express our concerns regarding CMS's proposal in the areas of breast cancer and gynecologic procedures. Specifically, we will address payment policy for the following items:

- Multiple Procedure Discounting
- Device Dependent Surgical Procedures
- New Technology
- Conversion Factor

Cytyc supports CMS in its endeavor to revise and develop a new ambulatory surgical center payment system under the requirement of the Medicare Modernization Act of 2003. Moreover a new ASC payment system modeled after the Hospital Outpatient Prospective Payment System (OPPS) seems to be the most appropriate and reasonable approach. However, as a company dedicated to women's health, we are quite concerned about certain areas in the proposed rule that we believe needs additional refinement and/or reform. Cytyc respectively requests CMS consider our comments and recommendations as presented below:

250 CAMPUS DRIVE • MARLBOROUGH, MA 01752 • TEL: (508) 263-2900 • FAX: (508) 229-2795

1. For breast brachytherapy codes; CPT 19296 and 19297, due to the high cost of this device, both CPT codes should be added to the list identified in Table 46 – Procedures Proposed for Exemption from Multiple Procedure Discounting, just as CPT 19298 is listed and the procedures are similar.

2. CMS should re-evaluate surgical services that require use of high-cost devices and ensure that procedures that are device-dependent are eligible for scheduling at an ASC.

3. CMS should consider how to address future technologies within the scope of the new ASC payment system allowing for payment under a New Technology APC and/or Pass-through type payment method for medical devices in the ASC setting.

4. CMS should establish a fair and reasonable ASC conversion factor.

   In addition, CMS should consider updating the annual ASC conversion factor using the hospital market basket as opposed to the CPI-U to adjust for inflation.

Cytyc Corporation, a medical device company, provides therapeutic and screening technologies for multiple areas of women's health. In the area of therapeutics, Cytyc manufactures the MammoSite® Radiation Therapy System (RTS) the most widely used method of breast brachytherapy to treat breast cancer and the NovaSure® System, the most widely used method of second generation endometrial ablation to treat abnormal uterine bleeding.

Payment Policy for Multiple Procedure Discounting

The proposed rule indicates CMS is proposing to mirror the OPPS policy for discounting when a beneficiary has more than one surgical procedure performed on the same day at an ASC. The policy is based on a simple count of procedures wherein the most costly procedure is paid the full amount and all other procedures are discounted by half. Of note, certain surgical procedures are not subject to the discounting policy – those exempted are generally surgeries performed to implant costly devices. They are not discounted even when performed in association with other surgical procedures because the cost of the implantable devices does not change, so resource savings due to efficiencies would be minimal. Please note the similarity in definitions below.

19296: Placement of radiotherapy afterloading balloon catheter into the breast for interstitial radioelement application following partial mastectomy, includes imaging guidance; on date separate from partial mastectomy

19297: Placement of radiotherapy afterloading balloon catheter into the breast for interstitial radioelement application following partial mastectomy, includes imaging guidance; concurrent with partial mastectomy

19298: Placement of radiotherapy afterloading brachytherapy catheters (multiple tube and button type) into the breast for interstitial radioelement application following (at the time of or subsequent to) partial mastectomy, includes imaging guidance

CMS has proposed the Exemption List from Multiple Procedures Discounting to include CPT 19298; however, CPT codes 19296 and 19297 are unlisted. While we are uncertain to this exclusion being an oversight, it should be noted that descriptor similarities exist between the three codes.

Cytyc requests that CMS consider coherence and consistency to the clinical characteristics, resource use and code descriptions relevant to breast brachytherapy codes 19296, 19297 and 19298 exempting all three codes from the multiple procedure discount. Additionally, we ask CMS update Table 46 and add CPT 19296 and 19297 listing the procedures exempt from multiple procedure discounting.

Device Dependent Surgical Procedures
For surgical procedures that utilize high-cost devices, often described "device-dependent" procedures, it is necessary to offer to the ASC the same purchasing opportunity the HOPD experiences. There are a number of surgical procedures that may be provided safely in the ASC, however, to date because of the purchasing limitations experienced by the ASC, access and choice is minimal for Medicare beneficiaries and their surgeons.

There is evidence that the ASC offers cost-effective surgical care, thereby, when a facility is disadvantaged by its inability to purchase devices for surgical procedures simply due to payment rates set below the cost of a device, this contributes to limiting access and moving procedures to the HOPD, traditionally recognized as a higher cost setting.

Breast Cancer Radiation
Cytyc manufactures the MammoSite® Radiation Therapy System (RTS), the most widely used method of breast brachytherapy. Breast brachytherapy targets radiation therapy where the radiation source is placed inside the tumor cavity via a special balloon catheter (i.e., MammoSite® RTS) and only delivers radiation to the area where cancer is most likely to recur. This technique limits radiation to healthy tissue, lungs and heart, thus reducing the likelihood of the possible side effects experienced during whole beam radiation. Unlike whole beam radiation where the woman requires 5-6 weeks of radiation every day, breast brachytherapy is *completed in 5 days*.

CPT 19296 and 19297
Breast brachytherapy codes 19296 and 19297 include a high-cost medical device and are bundled into the procedure payment, thus designating the surgical procedure device-dependent. The proposed payment methodology for a procedure that is device dependent will limit access in the ASC for procedures involving high-cost devices. Physicians and patients will be excluded from choosing the ASC as a preferred site of service for the catheter implant and will be forced to choose the HOPD due to reimbursement.

Abnormal Uterine Bleeding
Cytyc also manufactures the NovaSure® System which uses precisely controlled amounts of impedance controlled radio frequency energy to remove the endometrial lining of the uterus for abnormal uterine bleeding, also known as menorrhagia – a common disorder defined as excessive blood loss during menstruation. Women suffering from menorrhagia commonly use more than twenty sanitary napkins or tampons in a single day and often times miss work

and cannot participate in normal life activities such as caring for loved ones. The NovaSure® System, is approved to reduce or eliminate excessive menstrual bleeding due to benign causes in women who have completed childbearing. For women who have long suffered from menorrhagia, this next-generation option provides the possibility that their extreme symptoms will be relieved and their lifestyle improved, without a dramatic or extreme effect on their body. Second generation endometrial ablation technology provides alternatives to women who would typically undergo drug therapy, dilation & curettage (D&C), rollerball ablation, or hysterectomy. These second generation technologies provide a safe and less invasive alternative to treat this de-habilitating condition.

CPT 58563

Endometrial Ablation code 58563 also requires the use of a high-cost medical device bundled into the procedure payment, thereby categorizing the surgical procedure as device-dependent. The proposed payment methodology for a procedure that is device dependent will limit access in the ASC for procedures involving high-cost devices. Physicians and patients will be excluded from choosing the ASC as a preferred site of service for endometrial ablation, thus limiting access.

The Future in New Technology

As medical technology continues to evolve and develop, manufacturers will strive and continue to offer the health care delivery system new and innovative medical and surgical devices, as well as bringing to market diagnostic and therapeutic product advancements.

Bearing this in mind, we ask CMS to factor these certainties into the infrastructure of the new ASC Payment System so that payment to ASCs will continue to mirror that of the OPPS system inclusive of New Technology APCs and Pass-through payments.

ASC Conversion Factor

According to the Proposed Rule, CMS estimates a budget neutral ASC conversion factor for CY 2008 at $39.688 or approximately 62% of the CY 2008 estimated OPPS CF of $64.013.

While Cytyc acknowledges the final ASC CF may be higher or lower than $39.688 for a number of reasons as discussed in the Proposed Rule, our organization remains concerned that this proposed estimated conversion factor amount will further restrain ASC facilities from offering a full scope of available services to Medicare beneficiaries.
We understand that some stakeholders may have found potential errors in the calculation of the conversion factor. If so, we ask that CMS carefully consider any recommended corrections that may be submitted by those stakeholders. If the ASC fee schedule consists of rates that do not adequately meet ASC expenditures, the possibility exists that surgeries will not be scheduled in an ASC simply because of financial reasons and not because the ASC cannot safely provide high-quality, efficient, cost-effective surgical care.

As described in the Proposed Rule, updates to the ASC payment rates in the past have been based on the Consumer Price Index for all urban consumers (CPI-U). Beginning in CY 2008, CMS proposes to apply a CPI-U adjustment to update the ASC conversion factor for inflation on an annual basis. The CPI-U adjustment in CY 2008 and 2009 would equal zero.

We do not believe the statute requires the use of the CPI-U for future updates. We note that health spending has been increasing faster than inflation and that Congress found merit in linking the ASC payment system to the OPPS relative payment weights and APC groups. Therefore, adjustments of the ASC update based on the CPI are unreasonable and inconsistent with the update established for the OPPS. We believe the statutory language governing ASCs in the section 1833(i) of the Social Security Act provides the Secretary sufficient flexibility to permit the use of the hospital market basket to update the ASC payments and that the CPI-U is simply a default. Therefore, we recommend the use of the hospital market basket update for ASCs to provide consistent updates for both ASCs and hospital OPDs and better align the two payment systems.

Recommendations

CMS expects that a final rule implementing the revised ASC payment system will be published separately in the spring of 2007 with the revised payment system taking effect January 1, 2008.

Cytyc request that CMS consider posting another 'Proposed' Notice or Rule in the spring 2007 rather than a final rule. This would allow the public to further evaluate and provide comment of the CY 2008 ASC Payment system before the OPPS Final Rule is published on November 1, 2007 for CY 2008. It is our understanding CMS determined ASC services and the revised payment system would be brought in under and made part of the OPPS Rule combining and addressing both payment systems in one document with proposed and final updates. Alternatively should CMS decline our request, Cytyc would like to ask for a Town Hall Meeting sometime early 2007. The meeting would provide an opportunity for the public to hear from CMS as to the Agency's further refinement to the payment system based on comments received during this current comment period ending November 6, 2006.

Cytyc respectfully requests that CMS consider and implement the following recommendations:

1. For breast brachytherapy codes; CPT 19296 and 19297, due to the high cost of this device, both CPT codes should be added to the list identified in Table 46 – Procedures Proposed for Exemption from Multiple Procedure Discounting, just as CPT 19298 is listed and the procedures are similar.

2. CMS should re-evaluate surgical services that require use of high-cost devices and ensure that procedures that are device-dependent are eligible for scheduling at an ASC.

3. CMS should consider how to address future technologies within the scope of the new ASC payment system allowing for payment under a New Technology APC and/or Pass-through type payment method for medical devices in the ASC setting.

4. CMS should establish a fair and reasonable ASC conversion factor.

   In addition, CMS should update the annual ASC conversion factor using the hospital market basket as opposed to the CPI-U to adjust for inflation.

Should you have any questions or need additional information, please do not hesitate to contact me at 508-263-8958 or via email at margaret.eckenroad@ cytyc.com.

Sincerely,

Margaret Eckenroad
Senior Director, Women's Health
and Professional Relations

Submitter : **Dr. Brian Flanagan** **Date: 11/06/2006**

Organization : **Pinnacle Pain Medicine**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

I am disappointed by the proposed rule for ASC payments. My speciality, interventional pain management, will suffer substantially. For single speciality centers the proposed solutions are not feasible. I suggest that the proposal be reversed and a means be established where surgery centers are reimbursed at least at the present rate and will not go below that rate. I hope this will help in coming up with appropriate conclusions that will help the elderly in the United States.

Submitter : Mr. Gary Delanois

Date: 11/06/2006

Organization : Surgery Center of Southwest Florida

Category : Ambulatory Surgical Center

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE AND MEDICAID SERIVICES
OFFICE OF STRATEGIC OPERATIONS & REGULATORY AFFAIRS

Please note: We did not receive the attachment that was cited in this comment. We are not able to receive attachments that have been prepared in excel or zip files. Also, the commenter must click the yellow "Attach File" button to forward the attachment.

Please direct your questions or comments to 1 800 743-3951.

Submitter : **Dr. Vijay Singh** **Date: 11/06/2006**

Organization : **Niagara Health Center**

Category : **Ambulatory Surgical Center**

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1506-P2-1013-Attach-1.DOC

November 6, 2006

Leslie V. Norwalk, Esq., Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1506-P
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-1506-P - Medicare Program; the Ambulatory Surgical Center Payment System and CY 2008 Payment Rates
VIA FACSIMILE and ELECTRONICALLY

Dear Administrator Norwalk:

For the last few decades, Ambulatory surgery centers have been a high-quality, cost-effective alternative to inpatient hospital care for surgical services. As such, ASCs represent an important component of beneficiaries' access to surgical services; in some areas and specialties, 50% of the volume for certain procedures are being performed in ASCs. President Bush and his staff are on record, on multiple occasions, stating that ASCs are a more cost-effective environment than the hospital to receive key medical services.

Unfortunately, ASCs successful experience is facing regulatory challenges that could have a disastrous impact on their survival.

CMS is proposing to change the payment system for ambulatory surgery centers in 2008, linking payment to 62% of what CMS pays for services in the hospital outpatient department system (HOPD). Although we appreciate CMS's efforts to devise a new payment system, We remain very concerned regarding the impending cuts to reimbursement for ASCs procedures as the proposed system totally disregard the current costs associated with the procedure performed, . By setting payment rates at 62% of Hospital Outpatient departments, the new system will compromise further ASCs financial viability already affected by the payment freeze for nearly a decade. ASCs, typically small business, focused on a narrow spectrum of services,

have limited ability to respond to such drastic changes in payment system. They may no longer be able to meet their expenses and render a reasonable return on investment.

On the other hand, by setting rates this low, CMS would force physicians to respond to change by relocating their practice to a more expensive hospital setting, increasing expenditures for the government and beneficiaries. Such changes can have a significant effect on Medicare beneficiaries' access to services as well.

Conversion Factor: CMS explains the Conversion factor as follows-

'The conversion factor for ASC services would be less than for OPPS services, because of the greater efficiencies typical of ASCs and the generally lower costs incurred by ASCs. (For example, unlike hospitals, ASCs do not have to satisfy EMTALA requirements, do not run emergency departments, and do not have to be open 24 hours a day, seven days a week.) Due to the statutory ASC budget neutrality requirement, CMS estimates the CY 2008 ASC conversion factor would be 62 percent of the estimated CY 2008 OPPS conversion factor. We currently estimate the CY 2008 ASC CF to be $39.688."

We strongly disagree with the rational used by CMS to justify a cut of 38% in reimbursement for procedures performed in an ASC and not for those performed in a HOPD setting. CMS compares ASC costs and operation to hospital. This comparison made between hospital and ASCs is completely flawed as it amounts to comparing apples and oranges. Instead, CMS should align the conversion factor to HOPD since both settings operate the same way, are subject to the same standards and regulation:

- They both have to employ the same type of highly trained and compensated personnel (how could a Surgery center hire an RN for 62% of the cost paid by a hospital?) ASC have to satisfy the same patient's safety and the same accreditation than HOPD.
- HOPD do not provide a length of stay of more than 24 hours to their patients, hospitals do.
- ASCs do have to maintain emergency procedures to transfer patients with complications to a hospital for inpatient stay if needed. These occurrences are rare in ASCs reducing the cost of health care.
- ASCs have to provide the same supplies and equipment as the HOPD. How could they purchase them at 62% of the price paid by hospitals?
- Most importantly, ASCs are being hit by prohibitive increase in malpractice premium, health insurance for employees, and general liability insurance.

In sum, the proposed payment methodology, if adopted will violate basic management principles which could result in the closure of many if not most ASCs, will arbitrarily widen the gaps

between the two systems of payments, and the resulting disparities between the two systems will impede Medicare beneficiaries' ability to understand their real costs in alternative settings.

We urge CMS to re-evaluate its method for payment and develop reasonable and equitable uniform payment rates. And we hope that the new system will eliminate the distortions that exist between the two payment systems by expanding HOPD policies to ASCs when appropriate, specifically:

- Compensate ASCs for the same bundle services as are hospitals,
- Eliminate Cap on office-based payments,
- Update ASCs payments using market basket instead of consumer price index.

We appreciate the opportunity to comment on this important policy proposal and value the ongoing cooperation with you.

Sincerely,

Vijay Singh, MD
Chief Executive Officer,
Niagara Health Center
1601 Roosevelt Road,
Niagara, WI 54151

CMS-1506-P2-1014

Submitter : Dr. Ronald D. Castellanos **Date:** 11/06/2006

Organization : Southwest Florida Urologic Associates

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

Dear Ms. Norwalk:

I have reviewed the comments submitted by the AUA with regard to CMS-1506-P and I concur with them in their entirety. Your consideration of these comments will be greatly appreciated. See Attachment

Submitter : **Dr. Richard Sasnett** **Date: 11/06/2006**

Organization : **Augusta Urology Surgery Center, LLC**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1506-P2-1015-Attach-1.DOC

#1015

November 01, 2006

Leslie V. Norwalk, Esq., Acting Administrator
Centers for Medicare & Medicaid Services
Dept. of Health and Human Services
Attention: CMS-1506-P
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, Southwest
Washington, District of Columbia 20201

Dear Administrator Norwalk:

I am currently a member of a seven-physician urology practice in Augusta, Georgia. We have a freestanding ambulatory surgery center as well as three clinic offices in the surrounding area. We serve patients covered by private health insurance as well as an ever-growing Medicare/Medicaid and indigent population in our clinics as well as our surgery center. I am writing because there is current legislation pending that will drastically reduce Medicare ASC payments.

Augusta Urology Surgicenter is a high quality, cost effective alternative to the hospital. We play an important role in holding down the costs of medical care in the Augusta area. Therefore, I was disturbed to learn that Congress is considering proposals to cut our Medicare payments. Urology is expected to be the third hardest hit specialty in reductions to ASC Medicare payments. Mostly, this is due to the large reduction in the payment of the second most frequently performed Medicare ASC urologic procedure, prostate biopsy (CPT 55700). Payments for this procedure will be reduced by 39% in 2007 and even further in 2008.

I understand elected officials want to limit our facility fees to the hospital outpatient department rate (HOPD). While on paper a few of our rates appear to be higher than the hospital rate, this is very misleading. Our facility fee has to cover all the costs of our surgery, including radiology services. The hospital gets to bill separately for each of these as well as many other services. They also get to pass through the costs of new technology, but we cannot. By any standard, the hospital almost always gets paid much more for this and other procedures performed in this setting (outpatient).

As the actual impact of these reductions will vary among the different specialties, ultimately the financial viability of these enterprises will be negatively impacted. Instead of accomplishing the goal of more competition within the healthcare arena this will result in still fewer choices for Medicare recipients. This reimbursement philosophy greatly discourages the efficiency and excellence exhibited by a majority of surgery centers and does nothing to realistically reduce costs.

The proposal to reimburse surgery centers somewhere between 60-65% of hospital outpatient department rates is simply not adequate. Surgery centers must pay competitive wages to nurses and

other staff the same as hospitals. The increase in the cost for liability insurance coupled with the difficulty of obtaining coverage in some states has had a huge financial impact on surgery centers just as hospitals have experienced. Rent, taxes and operating supplies probably consume more of most surgery centers budgets than those of hospitals. Most surgery centers have 20-25 employees and are small businesses. They don't have the political clout and resources of large hospital organizations. If this were not so, this entire discussion and proposal would never had occurred.

Aligning the payment systems for ASCs with those of the hospital outpatient departments will improve the transparency of cost. In addition, improving the quality of the data generated by ASCs and hospital outpatient departments could only be positive for Medicare beneficiaries. We believe that the benefits to the taxpayer AND the Medicare consumer will be maximized by aligning the payment policies to the greatest extent permitted under the law.

In closing, we also believe the ASC list reform proposed by CMS is simply too limited. CMS should expand the list of procedures to mirror that of the HOPDs. ASCs are state licensed and Medicare approved facilities. Additionally a substantial number of ASCs are accredited by AAAHC and other respected accrediting bodies just as hospital outpatient departments. To allow HOPDs to perform any outpatient procedure but then restrict many of the same procedures from being performed in an ASC frankly makes no sense. The same physicians performing these procedures in the hospital outpatient suites are also owners and practitioners in ASCs. There is no deterioration in their surgical skills between facilities that we are aware. CMS should exclude only those procedures that are on the inpatient list.

Since ASCs must compete for labor, pay substantial sums for liability insurance and taxes, maintain all of the regulations mandated by CMS in addition to providing a safe, efficient and highly professional environment for Medicare patients, it is only equitable that CMS consider ASCs as equal partners in the medical services delivery system and not substandard enterprises.

Respectfully,

Richard B. Sasnett, Jr., M.D.
Augusta Urology Associates Surgicenter, LLC
Augusta, Georgia 30901

Submitter : **Dr. William P. Evans** **Date: 11/06/2006**

Organization : **Southwest Florida Urologic Associates**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

Dear Ms. Norwalk:

I have reviewed the comments submitted by the AUA with regard to CMS-1506-P and I concur with them in their entirety. Your consideration of these comments will be greatly appreciated. See Attachment.

Submitter : **Ms. Joyce Norman** **Date: 11/06/2006**

Organization : **Pacific Surgical Institute of Pain Management**

Category : **Ambulatory Surgical Center**

Issue Areas/Comments

CY 2008 ASC Impact

CY 2008 ASC Impact

PACIFIC SURGICAL INSTITUTE OF PAIN MANAGEMENT
3703 CAMINO DEL RIO SOUTH, STE 101, SAN DIEGO, CA, 92108
PHONEL619) 640-1555 FAX: (619) 640-9581

November 6, 2006

To: Centers for Medicare & Medicaid Services
Department of Health and Human Services

Dear Sirs,

I am an administrator for a small, physician owned Ambulatory Surgery Center. We are located in San Diego and provide a large volume of pain management and orthopedic services. I have been trying to decipher the changes that are on the horizon, and must say I have had great difficulty in doing so.

I have worked for this center for 8 years and have seen the difficulty first hand, in providing device intensive procedures to our medi-care patients. Historically we have lost money on any procedure which requires the use of specialty equipment (ie: laser, and such), orthopedic implants (ie: anchors, screws, etc.), and implantable devices such as intrathecal pumps and spinal cord stimulators. For the devices which were paid separately, the re-imbursement either barely covered the device, or came short of covering its cost.

While I understand that a free-standing facility does not have all of the same overhead as a hospital, we do pay the same prices from vendors for our surgical supplies and implants. By bundling the price of an implanted device into the payment rate, and cutting it by 38% you will be preventing our medi-care patients from receiving this care in an ASC. Unless pricing at the vendors end is controlled and regulated to fit with this system, the cost will always far outweigh the means. With our current pricing for an intrathecal pump, these changes would leave $325.00 to cover the cost of all medications, draping, sutures, fluoroscopy, staffing, anesthesia supplies, and any other costs. This is assuming we are able to re-coup the 20% that is the patient s responsibility (not an easy task, as these patients typically have such limited resources).
This is just one example of the inadequacy of the proposed system.

Cost efficient care is a necessity, and I am supportive of keeping the costs regulated. However, I must emphatically state that the proposed system will move a large volume of medi-care procedures back into the high cost hospital system. The ASCs must be re-imbursed, at least at cost, for implanted devices of any kind, so that the remainder of the re-imbursement fees can cover the cost of nursing staff, medications, sterile supplies, anesthesia supplies, fluoroscopic supplies, and the multitude of other items routinely used (which the 62% is also inadequate to cover).

I implore that you reconsider your plan before a great deal of hardship and failure occurs.
Sincerely,
Joyce Norman RN

Submitter : **Mr. Antonio Montecalvo** **Date: 11/06/2006**

Organization : **Organogenesis Inc.**

Category : **Private Industry**

Issue Areas/Comments

ASC Office-Based Procedures

ASC Office-Based Procedures

See attachment Section II.

ASC Office-Based Procedures

ASC Office-Based Procedures

See attachment Section III

CMS-1506-P2-1018-Attach-1.DOC

Organogenesis Inc.

LIVING TECHNOLOGY

150 Dan Road, Canton, Massachusetts 02021 • 781-575-0775 • FAX 781-401-1109

#1018

November 6, 2006

HAND DELIVERED

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-1506-P – Proposed Revised Ambulatory Surgery Center (ASC) Payment System and Related Regulation Changes

Dear Ms. Norwalk:

On behalf of Organogenesis Inc., the manufacturer of Apligraf®, I thank you for the opportunity to comment on Proposed Rule CMS-1506-P, "The Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates Proposed Rule" (the "Proposed Rule") published in the *Federal Register* on August 23, 2006. This letter offers comments with respect to section XVIII of the Proposed Rule which proposes a new payment system for services performed in the Ambulatory Surgery Center (ASC) for calendar year 2008.

We applaud your efforts to develop a new and more efficient ASC payment system. The new system in many respects will ensure increased access for Medicare beneficiaries and more efficient operation of the Medicare program in general. In particular, expanding the list of procedures covered in ASCs is a significant step towards improving the quality of care available to Medicare beneficiaries. Our comments and recommendations are intended to further this goal.

As discussed in detail below, Apligraf® is the ***only*** living, bi-layered tissue engineered product approved by the Food and Drug Administration ("FDA") for the treatment of diabetic foot ulcers (DFUs) and venous leg ulcers (VLUs). The CPT codes which describe the application of Apligraf®, 15340 Tissue cultured allogeneic skin substitute; first 25 sq cm or less, and 15341 Tissue cultured allogeneic skin substitute; each additional 25 sq cm, are proposed for addition to the list of services paid under the ASC payment system.

Unfortunately, under the proposed payment policy, Apligraf® - a proven, cost-effective product that has revolutionized wound care – will be unavailable to Medicare beneficiaries in the ASC setting. In order to make Apligraf® available, the Centers for Medicare and Medicaid Services (CMS) will need to make two revisions to its proposed payment policy:

- Amend the proposed packaging policy and provide separate reimbursement, for drugs and biologicals, including Apligraf®, that are <u>always</u> provided when a covered procedure is performed in an ASC; and

- Remove the proposed office-based designation of CPT code 15340 (Tissue cultured allogeneic skin substitute; first 25 sq cm or less), to ensure appropriate payment for performing this procedure.

We request that CMS make these revisions and discuss them in detail below.

I. <u>BACKGROUND ON APLIGRAF®</u>

By way of background, Apligraf® is the ***only*** living, bi-layered tissue engineered product approved by the Food and Drug Administration ("FDA") for the treatment of diabetic foot ulcers (DFUs) and venous leg ulcers (VLUs). Like human skin, Apligraf® consists of living cells and structural proteins. The lower dermal layer combines bovine type 1 collagen and human fibroblasts (dermal cells), which produce additional matrix proteins. The upper epidermal layer is formed by promoting human keratinocytes (epidermal cells) first to multiply and then to differentiate to replicate the architecture of the human epidermis.[1]

FDA regulates Apligraf® as a Class III medical device which required PreMarket Approval ("PMA"), the most rigorous form of FDA scrutiny for medical devices. Since its initial FDA approval in 1998, Apligraf® has been the subject of hundreds of peer-reviewed medical studies and is considered as "the evidence-based standard" for wound healing.

CMS regulates and reimburses Apligraf® as a biologic and it is paid for separately under both the physician fee schedule (PFS) and the Outpatient Prospective Payment System (OPPS). Regardless of whether Apligraf® is applied in a hospital or a physician office, Apligraf® is reported using HCPCS code J7340 and it is the only product crosswalked to J7340 for purposes of determining the average sales price (ASP) for J7340.[2]

Apligraf® is the only tissue cultured allogeneic skin substitute on the market. Accordingly, the Current Procedural Terminology (CPT) codes for the application of Apligraf® are 15340 (Tissue cultured allogeneic skin substitute; first 25 sq cm or less) and 15341 (Tissue cultured allogeneic skin substitute; each additional 25 sq cm). <u>**Apligraf® is used every time CPT codes 15340 and 15341 are furnished.**</u>

[1] Unlike human skin, Apligraf® does not contain melanocytes, Langerhans' cells, macrophages, and lymphocytes, or other structures such as blood vessels, hair follicles or sweat glands.

[2] Until 2006, Apligraf® was reported using HCPCS Code C1305 for the hospital setting and J7340 for the physician office setting. Apligraf® is now reported using J7340 for both the hospital <u>***and***</u> physician office setting. Apligraf® was and is the only product crosswalked to C1305 and J7340 for the purposes of determining ASP.

Apligraf® is widely used in the hospital setting but has not been used in ASCs for two reasons:

1. The CPT code(s) describing its use has not been on the list of procedures for which Medicare makes reimbursement under the ASC payment system; and
2. Medicare bundles payments for drugs and biologics into the payment it makes for procedures on the ASC list.

II. ASC PACKAGING - CMS SHOULD REVISE ITS ASC PACKAGING POLICY AND SEPARATELY REIMBURSE FOR APLIGRAF®

The expansion of the ASC procedure list is a significant and important improvement in the ASC system. However, the inclusion of CPT codes 15340 and 15341 on the ASC raises issues that, we believe, will require CMS to revise its ASC packaging policy for drugs and biologics. As noted above, Apligraf® is used every time CPT codes 15340 and 15341 are furnished. It has an ASP of $26.31/square centimeter,[3] which means that its "per unit" cost to Medicare is $1227.16 (ASP + 6%).[4]

Unless CMS makes separate payment for Aligraf, its decision to include CPT Codes 15430 and 15431 on the ASC list will be rendered meaningless because no ASC will provide those services if it is financially liable for the cost of Apligraf®. Instead, patients will be forced to obtain Apligraf® in a hospital outpatient department or a physician's office. In a hospital outpatient department, not only are there likely to be longer wait times, but copayments for the procedure will be significantly higher.

As discussed below, we recommend that CMS review all procedures proposed to be on the ASC list to determine which ones always require the use of a drug or biologic that is paid for separately under the PFS and/or OPPS. We also propose that CMS make separate payment for drugs and biologics when the following two conditions apply: (1) the drug or biologic is separately payable under the OPPS and the PFS, and (2) the code descriptor requires the administration of that drug or biologic.

A. The code for Apligraf®, J7340, is always associated with the CPT Codes describing the "application of Apligraf®".

As noted above, CPT codes 15340 and 15341 require the use of Apligraf® because Apligraf® is the only tissue cultured allogeneic skin substitute on the market. Furthermore, Apligraf® is reported using HCPCS code J7340 and it is the only product crosswalked to J7340 for purposes of determining the ASP for J7340. Therefore, assuming accurate claims submission, any claim for CPT codes 15340 and 15341 should contain a line item for J7340.

In the Proposed Rule CMS states that it performed a careful analysis of OPPS claims and was unable to find items such as drugs or biologics "that are repeatedly and consistently reported separately in association with specific ambulatory surgical procedures."[5] In addition, the

[3] October 2006 ASP pricing file accessed on October 30, 2006.
[4] Apligraf® is packaged as a 44 cm^2 disc.
[5] 71 Fed. Reg. 49,648 (August 23, 2006).

Proposed Rule asks commenters[6] to provide information about surgical procedures that are frequently performed in association with items that could be paid separately and to give reasons why they are associated.

The CPT codes (15300 – 15366) for application of various types of allografts and xenografts were completely revamped for 2006 and there are no claims data for any of those codes for any year prior to 2006. Therefore, in order to determine whether claims for application of Apligraf® are always associated with J7340, CMS must analyze claims data for the predecessor codes to 15340 and 15341. Those predecessor codes are 15342 (application of bilaminate skin substitute/neodermis; 25 sq cm) and 15343 (application of bilaminate skin substitute/neodermis; each additional 25 sq cm).

In summary, we believe that the CMS claims review of surgical procedures and associated ancillary items performed in the OPPS overlooked the applicable CPT codes for application of Apligraf®. *If CMS were to carefully review claims with CPT codes 15342 and 15343, the Agency would see that they are always -- not just "repeatedly and consistently" -- reported with J7340, a separately paid ancillary biologic.* Thus, we request that CMS repeat its analysis for these codes.

B. Inclusion of CPT codes 15340 and 15341 on the ASC procedure list means that ASCs will perform procedures that require separately paid items, such as Apligraf®.

In the Proposed Rule, CMS argues that ASCs are less likely to perform complex procedures on severely ill patients, and therefore will have less need to provide separately paid items and services.[7] It is unclear why CMS believes there is a connection between the performance of "complex" procedures and use of separately payable ancillary items. While it is true that many surgical procedures are performed without the use of any ancillary services other than anesthesia (which, of course, is not separately payable), this premise is overbroad.

Specifically, the application of Apligraf® is not a complex procedure. In fact, it is commonly performed in the outpatient hospital setting. CMS' proposal to add CPT codes 15340 and 15341 (i.e., the application of Apligraf®) to the ASC list for 2008 is appropriate because it is the type of procedure that can easily be performed in the ASC. However, those services always require the use of an expensive item (Apligraf®) that is separately payable in the outpatient hospital setting. In fact, if Apligraf® was NOT paid separately in the ASC setting, then it would never be used

[6] Specifically the rule states: "We are seeking comments from ASC clinical and administrative staff and from physicians who perform surgery at ASCs regarding nonsurgical ancillary services or items that are directly related to a surgical procedure that would be paid separately under the OPPS but that would be packaged under our proposal for the revised ASC payment system. We are specifically requesting that commenters provide data to indicate the frequency with which specific items and services are typically furnished in association with given procedures, the reasons why one patient might require the additional items and services whereas another patient would not, and the costs of those items and services relative to the other costs incurred to perform the associated surgery." 71 Fed. Reg. 49,648.

[7] The Proposed Rule states: "[W]e believe that ASCs generally treat a less complex and severely ill patient case mix and, as a result, we believe that ASCs are less likely to provide on a regular basis many of the separately paid items and services that patients might receive more consistently in a hospital outpatient setting." 71 Fed. Reg. 49,648.

because its cost is not included in the payment for the procedure and hospitals would be unable to bear the cost for its purchase without adequate reimbursement.

CMS is proposing to base ASC payments on the relative weights of procedures in the OPPS. While those relative weights do include the costs of certain medical devices they do NOT include the cost of expensive drugs and biologics, such as Apligraf®. CMS must maintain a consistent payment policy across all sites of service. **CMS does bundle the cost of medical devices, surgical supplies, and equipment in all settings but it does NOT bundle the cost of drugs and biologics in ANY setting except for the ASC.** While that bundling policy may be appropriate for procedures where the only drug administered is an anesthetic, it clearly is inappropriate for such procedures as CPT codes 15340 and 15341, which require an expensive biologic.

We applaud CMS' expansion of the ASC list to include CPT codes 15340 and 15341; however, we disagree with CMS' packaging proposal. CMS' expansion of the ASC list to include procedures that always require expensive drugs or biologics, like Apligraf®, means that CMS must revise its proposal to allow separate payment for those drugs or biologics. If the proposed packaging policy is finalized without revision, the presence of CPT codes 15340 and 15341 on the ASC list will be meaningless because without separate payment for Apligraf®, these codes will never be utilized in the ASC setting.

C. Making Separate Payment for Apligraf® will not Result in Dramatic Increases in Medicare Spending.

CMS raises a number of concerns in the Proposed Rule that led to its decision to not make separate payment for many ancillary items and services including drugs and biologics. Specifically, CMS states that it is concerned that unbundling of ancillary services would "reduce incentives for cost-efficient delivery of services at ASCs" and "increase the complexity" of the revised payment system.[8] Not only are these concerns unfounded with regard to making separate payment for Apligraf® (J7340), but by not making separate payment for Apligraf®, CMS will actually be creating an incentive for the provision of ineffective, costly wound care and making the inclusion of CPT codes 15340 and 15341 on the ASC list meaningless.

Apligraf® is proven to accelerate the healing of debilitating chronic wounds. Application of Apligraf® reduces the incidence of osteomyelitis and amputation associated with DFUs and VLUs. Therefore, Apligraf® actually reduces the cost of care by shortening the cost of treatment, reducing the number of debridements performed, and avoiding clinically severe and costly complications.

Use of CPT codes 15340 and 15341 will not be a meaningful option in the ASC setting unless CMS makes separate payment for Apligraf®. The reason is simple, just like hospitals, ASCs will not be able to bear the cost of purchasing Apligraf® without adequate reimbursement. In fact, not making separate payment for Apligraf® will result in creating a financial incentive for ASCs to perform additional, potentially unnecessary procedures such as wound debridements and surgeries that could have been avoided by the use Apligraf®. It will also shift care to the outpatient hospital setting where patient copayments are higher and patients will face longer

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[8] 71 Fed. Reg. 49,648.

waiting times. Accordingly, if CMS does not make separate payment for Apligraf® at ASCs, the end result will be a reduction in quality of care provided to Medicare beneficiaries.

In the past, CMS has stated that it intends to develop payment policies that will be site-of service neutral because it wants providers to base delivery of care decisions on clinical considerations and not on financial incentives to perform services at one site-of-service over another. In the unique case of Apligraf®, CMS' current proposal will actually achieve the opposite of this goal. It will provide an incentive for applying Apligraf® in the outpatient hospital or physician office setting which, as stated, could result in higher copayments for beneficiaries.

We are not recommending, nor do we believe, that CMS must make separate payment for ALL drugs and biologics in the ASC setting. Instead, we recommend that CMS consider, on a procedure-by-procedure basis, whether separate payment should be made for drugs and biologics used in association with that procedure. Specifically, we recommend that CMS review all procedures on the proposed ASC list and use the following criteria when determining whether to make separate payment for a drug or biologic:

- the code descriptor for the procedure requires that the drug or biologic be used in order to perform the procedure; and
- the drug or biologic also must be paid separately under the PFS and OPPS.

We believe that, ultimately, this would result in CMS only making separate payment for a very small number of drugs and biologics in the ASC setting. At a minimum, it will ensure that Medicare beneficiaries get appropriate access to Apligraf® in an ASC.

III. ASC OFFICE-BASED PROCEDURES - CPT CODE 15340 IS NOT AN OFFICE-BASED PROCEDURE

Again, Organogenesis supports your proposal to expand the ASC list to make payment for any procedure that does not pose a significant safety risk to patients and does not require an overnight stay. Under the Proposed Rule factors such as whether the procedure is commonly performed in the physician office setting are no longer relevant for determining whether a procedure may be paid in the ASC setting.

However, whether a procedure is office-based is still highly relevant for determining the reimbursement level for a procedure performed in the ASC setting. Under the Proposed Rule, payment for procedures determined to be office-based will be limited to the lesser of the PFS non-facility practice expense amount, or the ASC rate under the revised ASC payment system.[9]

The Proposed Rule indicates that a procedure would NOT be designated as office-based if: (1) BESS claims data indicates the procedure is performed less than 50 percent of the time in the office setting,[10] (2) the procedure is on the ASC-approved procedure list for CY2007,[11] or (3) a code-by-code clinical analysis by CMS medical advisors results in a determination that the code

[9] 71 Fed. Reg. 49,650.
[10] 71 Fed. Reg. 49,649.
[11] 71 Fed. Reg. 49,650.

should not be office-based.[12] CMS designated CPT code 15340 as office-based and its payment is subject to the proposed PFS cap as described above. For the reasons stated below we believe this designation is erroneous.

A. Claims data for the predecessor code to 15340 shows that the 15340 should not have been designated as office-based.

CPT code 15340 is new for CY 2006, therefore, site-of-service claims data for it are unavailable. This means that claims data for the predecessor code, CPT code 15342, must be analyzed to determine whether 15340 should be designated as office-based. CMS used BESS data to determine that 15340 should be designated as office-based. We believe the designation is erroneous and the use of BESS data was inappropriate.

We engaged The Moran Company to determine the percentage of procedures performed in the office setting. Moran examined all data files that contained site-of-service information. After this review, they used the OPPS rate setting file to determine the number of services furnished in the outpatient hospital setting and the Physician/Supplier Procedure Summary (PSPS) master file to determine the number of services furnished in the physician office and ASC settings. Moran found these files to be more accurate than BESS data because the PSPS master file is more comprehensive and because using BESS data to determine outpatient hospital services can result in double counting. The Moran Company analysis is attached for your review.

The Moran Company analysis using the predecessor code shows that more than two-thirds of the procedures involving Apligraf® were performed in the outpatient hospital setting and less than one-third were performed in the physician office. Therefore, by CMS' own proposed claims-based criterion, 15340 should NOT be designated as office-based.

B. CPT code 15340 is the only code among the entire list of codes describing application of allografts and xenografts to be designated as office-based.

CPT code 15340 is only one of many CPT codes (15300-15366) that describe application of allografts and xenografts. All of these procedures are clinically similar and require similar resources to perform, yet CPT code 15340 is the only procedure to be designated as office-based.

In fact, this clinical similarity has been recognized by CMS itself. In the OPPS, CPT code 15340, like almost all the other codes describing allografts and xenografts, has been placed in APC 25. This is an affirmative acknowledgement from CMS that all the procedures in the range use similar resources. CMS should, therefore, pay for all these procedures similarly in the ASC setting just as it does in the OPPS.

Not only is it inconsistent from a policy perspective to designate 15340 as office-based, but it creates a financial incentive for ASCs to use other types of allografts and xenografts for treatment of wounds. Such an incentive is completely inconsistent with Medicare's policy goals of not allowing financial considerations to drive medical decisions, and to promote value-based purchasing.[13] Moreover, designating CPT code 15340 as office-based also may reduce the

[12] 71 Fed. Reg. 49,650-49,651.
[13] 71 Fed. Reg. 49,650.

quality of patient care because most other allografts and xenografts are not FDA-approved for treatment of chronic wounds.

We realize that a number of the allograft and xenograft procedure codes are on the ASC list for CY 2007 and are therefore not eligible for designation as office-based because of the CMS proposed "grandfathering" rule. However, due to the reasons set forth above, and as a matter of fairness, we believe that CPT code 15340 should be treated the same from a payment perspective as all the other codes describing allografts and xenografts.

In short, the proposed office-based designation for CPT code 15340 is not supported by claims data or by clinical review. It creates an inappropriate financial incentive to use potentially less effective products on Medicare beneficiaries and should not be finalized.

IV. CONCLUSION

In summary, we request that CMS modify its proposed packaging policy for drugs and biologics and allow separate payment for certain drugs and biologics, such as Apligraf®, that are required in order to perform a covered procedure in an ASC and which are already separately paid under the PFS and the OPPS. We also request that CMS withdraw its designation of 15340 as office-based.

Organogenesis would again like to thank CMS for the opportunity to submit formal comments on the Proposed Rule. We urge CMS to adopt the recommendations set forth in this comment letter so that Medicare beneficiaries continue to have access to the most advanced and effective treatment for chronic wounds. Without a change, physicians will be unable to provide the most advanced treatment, beneficiaries will be forced to suffer poorer health outcomes, and ultimately the Medicare program will see higher health costs.

Sincerely,

Antonio Montecalvo
Director, Customer Support Services

Attachment:
Analysis of The Moran Company
Relevant 2005 Medicare Volume Data

THE MORAN COMPANY

2005 Medicare Volume Data

Prepared for Organogenesis
Source: 2005 Physician Supplier/Procedure Summary File

CPT CODES	Alwd Units ASC (facility)*	Alwd Units OFFICE**	Alwd Units HOPD***	% OFFICE	% HOPD
15340		-	-		
15342	-	7,848	15,973	33%	67%
15343	-	1,197	3,281	27%	73%
15350	121	1,414	3,625	28%	72%
15351	2	14	220	6%	94%
15400	435	4,962	1,939	72%	28%
15401		9	73	11%	89%

**measure of allowed facility claims for performing procedure in the ASC*
***measure of allowed professional service claims for performing procedure in the Physician Office*
****measure of allowed professional service claims for performing procedure in the HOPD*

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Submitter : **Dr. Francis W. Price, Jr.** **Date: 11/06/2006**

Organization : **Central Indiana Surgery Center**

Category : **Ambulatory Surgical Center**

Issue Areas/Comments

ASC Ratesetting

ASC Ratesetting

My name is Francis W. Price Jr., MD and I operate a small ASC in Indianapolis, Indiana. I am submitting these comments to express my concern about the proposed regulation to establish a new ASC payment system and updated ASC procedures list.

Our surgery center has been in operation for 12 years and we have always strived to provide exceptional surgical care for the best possible fees. I am committed to high quality and lower cost cataract and other ophthalmic surgical care, and I see the current proposal as problematic.
Our facility performs cataract, specialized cornea transplants, glaucoma and other ophthalmic surgeries. We serve approximately 486 Medicare patients annually.

I feel the proposed reform of the ASC procedures list remains far too restrictive. I feel the decision as to the site of the surgery should be made by the surgeon in consultation with the patient. ASCs should be permitted to furnish and receive facility reimbursement for any and all procedures that are performed in HOPDs.

Your proposal to pay ASCs only 62% of the procedural rates paid to HOPDs is wholly inadequate and doesn't reflect a realistic differential of the costs incurred by hospitals and ASCs in providing the same services. I feel a more adequate reimbursement would be 85%. Whatever percentage is eventually adopted by CMS in the final regulation, it should be applied uniformly to all ASC services, regardless of the type of procedure or the specialty of the facility. Under the current and proposed rates, physician owned ASCs can not effectively perform retinal procedures, and it is difficult to continue providing services for complex procedures like we do to correct difficulties with intraocular lenses and corneal degenerations. Realistically, hospitals and ASCs should be a level playing field and making it that way would dramatically reduce the cost to the Medicare system.

Under current law, ASCs are provided no annual cost-of-living updates from 2004 - 2009, notwithstanding significant increases in the costs of delivering care. Commencing in 2010, CMS is proposing to pay ASCs an update equal to the consumer price index, while HOPDs would be paid an update based on the hospital market basket, which is typically higher. The new payment system should provide hospital market basket updates to both ASCs and HOPDs since both provide the same services and incur the same costs in delivering high quality surgical care.

Sincerely,

Francis W. Price Jr., MD

Medical Director
Central Indiana Surgery Center
9002 North Meridian Street, Lower Level
Indianapolis, IN 46260
317-848-1763

Submitter : **Dr. James Carswell, III** **Date: 11/06/2006**

Organization : **Augusta Urology Surgery Center, LLC**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1506-P2-1020-Attach-1.DOC

#1020

November 01, 2006

Leslie V. Norwalk, Esq., Acting Administrator
Centers for Medicare & Medicaid Services
Dept. of Health and Human Services
Attention: CMS-1506-P
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, Southwest
Washington, District of Columbia 20201

Dear Administrator Norwalk:

I am currently a member of a seven-physician urology practice in Augusta, Georgia. We have a freestanding ambulatory surgery center as well as three clinic offices in the surrounding area. We serve patients covered by private health insurance as well as an ever-growing Medicare/Medicaid and indigent population in our clinics as well as our surgery center. I am writing because there is current legislation pending that will drastically reduce Medicare ASC payments.

Augusta Urology Surgicenter is a high quality, cost effective alternative to the hospital. We play an important role in holding down the costs of medical care in the Augusta area. Therefore, I was disturbed to learn that Congress is considering proposals to cut our Medicare payments. Urology is expected to be the third hardest hit specialty in reductions to ASC Medicare payments. Mostly, this is due to the large reduction in the payment of the second most frequently performed Medicare ASC urologic procedure, prostate biopsy (CPT 55700). Payments for this procedure will be reduced by 39% in 2007 and even further in 2008.

I understand elected officials want to limit our facility fees to the hospital outpatient department rate (HOPD). While on paper a few of our rates appear to be higher than the hospital rate, this is very misleading. Our facility fee has to cover all the costs of our surgery, including radiology services. The hospital gets to bill separately for each of these as well as many other services. They also get to pass through the costs of new technology, but we cannot. By any standard, the hospital almost always gets paid much more for this and other procedures performed in this setting (outpatient).

As the actual impact of these reductions will vary among the different specialties, ultimately the financial viability of these enterprises will be negatively impacted. Instead of accomplishing the goal of more competition within the healthcare arena this will result in still fewer choices for Medicare recipients. This reimbursement philosophy greatly discourages the efficiency and excellence exhibited by a majority of surgery centers and does nothing to realistically reduce costs.

The proposal to reimburse surgery centers somewhere between 60-65% of hospital outpatient department rates is simply not adequate. Surgery centers must pay competitive wages to nurses and

other staff the same as hospitals. The increase in the cost for liability insurance coupled with the difficulty of obtaining coverage in some states has had a huge financial impact on surgery centers just as hospitals have experienced. Rent, taxes and operating supplies probably consume more of most surgery centers budgets than those of hospitals. Most surgery centers have 20-25 employees and are small businesses. They don't have the political clout and resources of large hospital organizations. If this were not so, this entire discussion and proposal would never had occurred.

Aligning the payment systems for ASCs with those of the hospital outpatient departments will improve the transparency of cost. In addition, improving the quality of the data generated by ASCs and hospital outpatient departments could only be positive for Medicare beneficiaries. We believe that the benefits to the taxpayer AND the Medicare consumer will be maximized by aligning the payment policies to the greatest extent permitted under the law.

In closing, we also believe the ASC list reform proposed by CMS is simply too limited. CMS should expand the list of procedures to mirror that of the HOPDs. ASCs are state licensed and Medicare approved facilities. Additionally a substantial number of ASCs are accredited by AAAHC and other respected accrediting bodies just as hospital outpatient departments. To allow HOPDs to perform any outpatient procedure but then restrict many of the same procedures from being performed in an ASC frankly makes no sense. The same physicians performing these procedures in the hospital outpatient suites are also owners and practitioners in ASCs. There is no deterioration in their surgical skills between facilities that we are aware. CMS should exclude only those procedures that are on the inpatient list.

Since ASCs must compete for labor, pay substantial sums for liability insurance and taxes, maintain all of the regulations mandated by CMS in addition to providing a safe, efficient and highly professional environment for Medicare patients, it is only equitable that CMS consider ASCs as equal partners in the medical services delivery system and not substandard enterprises.

Respectfully,

James J. Carswell, III, M.D.
Augusta Urology Associates Surgicenter, LLC
Augusta, Georgia 30901

Submitter : **Dr. James D. Borden** **Date: 11/06/2006**

Organization : **Southwest Florida Urologic Associates**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

Dear Ms. Norwalk:

I have reviewed the comments submitted by the AUA with regard to CMS-1506-P and I concur with them in their entirety. Your consideration of these comments will be greatly appreciated. See Attachment.

CMS-1506-P2-1021-Attach-1.DOC

#1021

November 6, 2006

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1506-P
P.O. Box 8011
Baltimore, MD 21244-1850

Re: **CMS-1506-P** – Medicare Program; Ambulatory Surgical Center Payment System and CY 2008 Payment Rates; Proposed Rule

Dear Ms. Norwalk:

On behalf of the American Urological Association (AUA), representing 10,000 practicing urologists in the United States, I am pleased to submit comments on the Centers for Medicare & Medicaid Service's (CMS) proposed rule for reforming the Ambulatory Surgical Center (ASC) Payment System. The AUA understands that this reform proposal, as mandated by the 2003 Medicare Modernization Act (MMA) has been a huge undertaking for CMS and appreciates the time and effort CMS has put into development of the proposal. We also appreciate CMS holding a listening session teleconference in August 2005 and for meeting with the AUA and other groups that are interested in ASC payment reform over the past couple of years.

We understand that the MMA places certain limitations, the major one being a budget-neutrality requirement, on CMS's discretion in developing an ASC payment reform proposal. However, CMS does have a certain degree of discretion in how it implements the MMA, and we hope that CMS we consider suggestions that would improve the reform proposal to the extent that the suggestions are within CMS's discretion to implement them.

ASC PAYABLE PROCEDURES

Under the proposal, Medicare would allow payment of an ASC facility fee for any surgical procedure performed in an ASC, except those that CMS determines are not payable under the ASC benefit based on the principal clinical considerations of beneficiary safety and the need for an overnight stay. CMS also proposes to discontinue the current time-based criteria of procedures that exceed 90 minutes of operating time, 4 hours of recovery time or 90 minutes of anesthesia. The AUA applauds CMS for proposing these changes to the ASC list as they are a big improvement over some of the current outdated rules that govern the ASC list. We also offer the following comments regarding the specific criteria for defining a significant safety risk and the need for an overnight stay.

Procedures that could pose a significant safety risk

CMS proposes to define procedures that could pose a significant safety risk as:

- any procedure included on the OPPS inpatient-only list
- procedures performed 80 percent or more of the time in the hospital inpatient setting
- procedures that involve major blood vessels; prolonged or extensive invasion of body cavities; extensive blood loss or are emergent or life-threatening in nature

The AUA disagrees with the criteria of procedures performed 80 percent or more of the time in the hospital inpatient setting, and urges CMS to delete this as one of the criteria for procedures that could pose a significant safety risk. We feel that the 80 percent cut-off is arbitrary and we are concerned that this criterion could artificially restrict the natural movement of procedures among sites of service that technological developments may allow for. Also, because the determination of whether procedures meet the 80 percent cut-off would be based on Medicare site-of-service data, a lag in data collection could also artificially restrict the movement of procedures into the less-expensive ASC setting. Furthermore, use of Medicare data does not allow consideration of site-of-service trends in non-Medicare populations.

Overnight stay:
CMS is also proposing to exclude from payment any procedure for which prevailing medical practice dictates that the beneficiary will typically be expected to require active medical monitoring and care at midnight following the procedure. The AUA opposes this blanket criterion for excluding procedures from the ASC list, as many ASCs have the capability to deal with these types of situations and physicians would not choose to do procedures in an ASC if they felt there was a possibility of having to admit the patient to the hospital. Physicians make these decisions using their clinical judgment based on the patient's anesthesia risk as determined by the patients' score based on the American Society of Anesthesiologist's Physical Status Classification System.

Proposed definition of surgical procedures
CMS proposes to define surgical procedures as any procedure within the CPT code range of 10000 to 69999, but seeks comments on whether all services contained in this range are appropriately defined as surgery. For example, CMS asks whether office-based procedures or procedures that require relatively inexpensive resources to perform should be excluded from the ASC list. The ability of a physician to select the most appropriate site of service for their patients based on clinical considerations is extremely important. Therefore, the AUA agrees that any procedure within the "Surgery" section of CPT should continue to be defined as a surgical procedure eligible for payment under the revised ASC payment system, regardless of whether it is office-based or requires relatively inexpensive resources to perform.

We also note, however, that modern surgical techniques also include a number of radiology procedures that are invasive in nature and that are integral to the performance of other surgical procedures. Examples include stone removal, balloon dilation of strictures and prostate biopsies. To allow for the efficient performance of these procedures in ASCs, we believe the revised ASC payment system's definition of surgical procedure should be expanded to include invasive radiology procedures that require the insertion of a needle, catheter, tube or probe through the skin or into a body orifice and intraoperative radiology procedures that are integral to the

performance of a non-radiological surgical procedure and performed during the non-radiological surgical procedure or immediately following the surgical procedure to confirm placement of an item, such as ultrasound used to provide guidance for biopsies and major surgical procedures or to determine, during surgery, whether surgery is being conducted successfully. The physician self-referral regulations also carve out these invasive and intraoperative radiology services from the definition of "radiology" services subject to the law's self-referral prohibition. This Stark law exclusion is based "on the theory that the radiology services in these procedures are merely incidental or secondary to another procedure that the physician has ordered" and, thus, are less subject to abuse from overutilization. 63 Fed. Reg. 1645, 1676 (Jan. 9, 1998).

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CMS proposes to base ASC relative payment weights on Ambulatory Payment Classification (APC) groups and relative payment weights established under the OPPS based on the belief that the relative payment weights established under the OPPS for procedures performed in the outpatient hospital setting reasonably reflect the relative resources required for such procedures and do so with sufficient coherence to be applicable to other ambulatory sites of service. The AUA agrees that the OPPS APC groups are appropriate for use in the ASC payment system and that tying ASC payments to OPPS payments will create transparency and continuity across the continuum of ambulatory settings.

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Therefore, CMS proposes to cap payment for office-based surgical procedures for which an ASC facility fee would be allowed under the new payment system at: the lesser of the Medicare physician fee schedule nonfacility practice expense payment or the ASC rate under the revised ASC payment system. CMS also proposes to exempt procedures that are on the ASC list as of January 1, 2007 that meet the criterion for designation as office-based, from the payment limitation proposed for office-based procedures.

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Proposal to phase in implementation of payment rates

CMS proposes to implement the revised ASC payment system in 2008 using transitional payment rates that would be based on a 50/50 blend of the payment rate for procedures on the 2007 list of approved ASC procedures and the payment rate for that procedure calculated under the revised payment methodology. Procedures added in 2008 would be paid the full amount calculated under the revised methodology, and new rates would be fully implemented in 2009. The AUA supports a two-year phase in for the new ASC payment rates.

ASC CONVERSION FACTOR

Based on CMS's proposed methodology for calculating the ASC payment system conversion factor, it would equate to 62 percent of the OPPS conversion factor, or $39.688. Although we understand that CMS must implement ASC payment reform in a budget-neutral fashion as required by Congress, it is completely unreasonable to assume that the cost of furnishing any given procedure in an ASC is only 62 percent of the cost of furnishing the same procedure in a hospital outpatient department. We urge CMS to use its discretion to institute changes in the methodology in order to reach a more reasonable and credible conversion factor.

Thank you for considering our comments. If you have any questions or need additional information, contact Robin Hudson, AUA Manager of Regulatory Affairs, at 410-689-3762 or rhudson@auanet.org.

Sincerely,

Lawrence S. Ross, M.D.
President

Submitter : **Dr. Ronald D. Castellanos** **Date: 11/06/2006**

Organization : **Southwest Florida Urologic Associates**

Category : **Physician**

Issue Areas/Comments

GENERAL

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Dear Ms. Norwalk:

I have reviewed the comments submitted by the AUA with regard to CMS-1506-P and I concur with them in their entirety. Your consideration of these comments will be greatly appreciated. See Attachment.

CMS-1506-P2-1022-Attach-1.DOC

#1022

November 6, 2006

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1506-P
P.O. Box 8011
Baltimore, MD 21244-1850

Re: **CMS-1506-P** – Medicare Program; Ambulatory Surgical Center Payment System and CY 2008 Payment Rates; Proposed Rule

Dear Ms. Norwalk:

On behalf of the American Urological Association (AUA), representing 10,000 practicing urologists in the United States, I am pleased to submit comments on the Centers for Medicare & Medicaid Service's (CMS) proposed rule for reforming the Ambulatory Surgical Center (ASC) Payment System. The AUA understands that this reform proposal, as mandated by the 2003 Medicare Modernization Act (MMA) has been a huge undertaking for CMS and appreciates the time and effort CMS has put into development of the proposal. We also appreciate CMS holding a listening session teleconference in August 2005 and for meeting with the AUA and other groups that are interested in ASC payment reform over the past couple of years.

We understand that the MMA places certain limitations, the major one being a budget-neutrality requirement, on CMS's discretion in developing an ASC payment reform proposal. However, CMS does have a certain degree of discretion in how it implements the MMA, and we hope that CMS we consider suggestions that would improve the reform proposal to the extent that the suggestions are within CMS's discretion to implement them.

ASC PAYABLE PROCEDURES

Under the proposal, Medicare would allow payment of an ASC facility fee for any surgical procedure performed in an ASC, except those that CMS determines are not payable under the ASC benefit based on the principal clinical considerations of beneficiary safety and the need for an overnight stay. CMS also proposes to discontinue the current time-based criteria of procedures that exceed 90 minutes of operating time, 4 hours of recovery time or 90 minutes of anesthesia. The AUA applauds CMS for proposing these changes to the ASC list as they are a big improvement over some of the current outdated rules that govern the ASC list. We also offer the following comments regarding the specific criteria for defining a significant safety risk and the need for an overnight stay.

Procedures that could pose a significant safety risk

CMS proposes to define procedures that could pose a significant safety risk as:

- any procedure included on the OPPS inpatient-only list
- procedures performed 80 percent or more of the time in the hospital inpatient setting
- procedures that involve major blood vessels; prolonged or extensive invasion of body cavities; extensive blood loss or are emergent or life-threatening in nature

The AUA disagrees with the criteria of procedures performed 80 percent or more of the time in the hospital inpatient setting, and urges CMS to delete this as one of the criteria for procedures that could pose a significant safety risk. We feel that the 80 percent cut-off is arbitrary and we are concerned that this criterion could artificially restrict the natural movement of procedures among sites of service that technological developments may allow for. Also, because the determination of whether procedures meet the 80 percent cut-off would be based on Medicare site-of-service data, a lag in data collection could also artificially restrict the movement of procedures into the less-expensive ASC setting. Furthermore, use of Medicare data does not allow consideration of site-of-service trends in non-Medicare populations.

Overnight stay:
CMS is also proposing to exclude from payment any procedure for which prevailing medical practice dictates that the beneficiary will typically be expected to require active medical monitoring and care at midnight following the procedure. The AUA opposes this blanket criterion for excluding procedures from the ASC list, as many ASCs have the capability to deal with these types of situations and physicians would not choose to do procedures in an ASC if they felt there was a possibility of having to admit the patient to the hospital. Physicians make these decisions using their clinical judgment based on the patient's anesthesia risk as determined by the patients' score based on the American Society of Anesthesiologist's Physical Status Classification System.

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